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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,006	11/08/2000	Akihiro Kisheshita	197759USBCONT	1289

22850 7590 03/14/2003

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EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/708,006

Applicant(s)

KISHISHITA ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2002 has been entered.

Current Status

2. This action is responsive to Applicants' Reply and Request for Reconsideration of 30 December 2002 in Paper No 21.
3. Receipt and entry of Applicants' declaration is acknowledged.
4. Claims 1-15 are pending.
5. The Declaration under 37 C.F.R. §1.132 of Kashiwagi has been care fully considered but is not considered persuasive for the reasons set forth below.
5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al (US 4,810,818 03-1989) and further in view of Nofre et al (US 5,480,668 01-1996).

The instantly claimed invention is a crystalline form of the Aspartame derivative Neotame, and compositions comprising it.

Wakamatsu teaches (Column 3, lines 11-43) a method of producing a more easily soluble crystalline form of aspartame which comprises granulation and drying the aspartame to a water content of 2.6% by weight. Wakamatsu further teaches (Column 2, lines 17-18) a range of granule size of 0.1 to 10 mm which embraces the instant range of 100-1,400 μm (which corresponds to 0.1-1.4 mm).

The difference between the instant invention and that taught by Wakamatsu is that Wakamatsu does not suggest the use of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester (Neotame) in this process to create a more soluble form of neotame.

Nofre, however, teaches (Column 4, line 65-Column 5, line 10) Neotame and its synthesis (Column 6, lines 27-54) from Aspartame to which it is a close analog. Nofre further teaches (Column 1, lines 10-19) the use of Neotame as a sweetening agent in food and drinks as well as its use (Column 6, lines 16-26) in conjunction with other sweeteners such as sucrose and saccharin. Nofre further teaches (Column 6, lines 8-16) its use in conjunction with carriers or bulking agents such as polydextrose, starch, maltodextrins, and cellulose. Nofre teaches (Column 4, lines 29-37) the use of Neotame for all uses of the known sweetener aspartame.

Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art. The motivation for performing this invention would have been to provide the same improved solubility for Neotame that the process of Wakamatsu provided for its close analog Aspartame, a commercially important sweetener. Because of the

very close structural similarity of Neotame and Aspartame and the large overlap in their chemical and physiological behavior and intended uses the expectation for success would have been reasonable.

Response to Remarks

6. Applicant has made several remarks with regard to this rejection:

- a. Applicants argue that the C type crystals of the present claims are distinct from the A-type crystals afforded by one of the cited references. The Examiner agrees but points out that the rejection of record requires the application of the process of Wakematsu to the Neotame taught by Nofre. The Examiner does not contend that Nofre itself teaches the instant invention.
- b. Applicants argue that there is no teaching of the C-type crystals in Nofre. The Examiner agrees and points out that Wakematsu teaches that a more soluble crystalline form may be achieved by drying the Neotame analogue, Aspartame, to a lower (non-zero) water content. The demonstration that Nofre does not produce a C-type crystal is insufficient to overcome the rejection of record.
- c. Applicants further argue that the existence of motivation (the presence of which is acknowledged by Applicants) to carry out an invention is not sufficient to establish obviousness -a reasonable expectation of success must also be present. The Examiner agrees and points out that the close structural analogy between Neotame and Aspartame would have provided a reasonable expectation for success since, as analogues, they would have been expected

to have similar physical properties. This is underscored by the observation that both compounds have similar organoleptic properties. Organoleptic properties are well understood to be extremely sensitive to structural variation.

- d. Applicants cite the duly executed declaration under 37 C.F.R. §1.132 of Kashiwagi and argue that polymorph or pseudopolymorph related crystal forms exhibit different physical properties and can have a large influence on the industrial processing thereof. Applicants further argue that the discovery of a new crystal form of a known compound is unexpected. The Examiner disagrees, in this instance, that the discovery of a new crystal form is surprising. Wakamatsu teaches one of ordinary skill in the art to expect that the analogues of Aspartame (of which Neotame is one) may be expected to exhibit different crystalline forms depending upon water content. Wakamatsu provides the process for obtaining the new, more soluble, crystalline form as well. Applicants have simply applied the process taught by Wakamatsu and characterized the expected result.
- e. Applicants further argue that no prior art reference has been cited that stands for the proposition that the mere existence of one crystal form for a given compound suggests the existence of another different form for that compound. The Examiner agrees and points out that this point is not at issue in the rejection of record and support for this concept is not, therefore, required. One of ordinary skill in the art would have been motivated to apply

the process of Wakematsu to the Neotame of Nofre in order to produce a more industrially acceptable form of Neotame and not to produce the instantly claimed crystalline structure. Applicants have simply characterized the properties of the expected improved material. Because Wakematsu provides both the process for obtaining Applicants' crystalline form and the motivation to apply it to Neotame, Applicants' invention is considered by the Examiner to have been placed in the possession of the public by the combination of Wakematsu and Nofre (See: In re Grose and Flanigen, 201 USPQ 57).

Applicant's arguments filed 30 December 2002 have been fully considered but they are not persuasive for the reasons set forth above.

Conclusion

7. Claims 1-15 are outstanding. Claims 1-15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.


Application/Control Number: 09/708,006

Art Unit: 1621

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker
Patent Examiner
Technology Center 1600

March 13, 2003



Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600